REMARKS

Claims 1-46 remain in this application. The following Claims have been amended herein: Independent Claim 1 (and its dependent Claims 2, 11-18, 24-25, 28-30, and 32-33); and Independent Claims 44, 45, and 46.

According to the amendments herein made and the following remarks, the Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

1. Rejections Under 35 USC § 102

The Examiner had rejected Claims 1-27, 29-37, and 39-46 under 35 USC 102(e) as anticipated by U.S. Patent Application Publication No. 2003/0060873 ("Gertner").

More specifically, as to this ground for rejection, the Office Action stated the following:

> ". . .
> Regarding claims 1, 2, 6, 17, 18, and 44-46, Gertner et al. disclose a stent (Fig 1, element 12) comprising a scaffold constructed from a first material and with a porous outer surface comprising a coating (10) with pores (14). The stent is coated with a metallic matrix, which has pores containing a composite material comprising a plurality of particles of a bioactive agent stored in an erodable polymer (para 0011, 0050).
> Regarding claims 3-5, Gertner et al. disclose the outer diameter of the particles is less than about 1 micron (para 0050).
> Regarding claims 7-10, Gertner et al. disclose the inner diameter of the pores is substantially equivalent to the outer diameter of the particles since the bioactive material particles are co-deposited along with the metal (para 0052) and thus the inner diameter of the pores is less than about 1 micron (para 0050; 0065).
> Regarding claim 11, Gertner et al. disclose the porous outer surface may comprise a material that is inherently porous (para 0044).
> Regarding claim 12-15, Gertner et al. disclose the porous outer surface may comprise a material that is not inherently porous, and the pores are etched into the material (para 0044).
> Regarding claim 16, Gertner et al. disclose the porous outer surface may comprise a sintered material (para 0009).

Regarding claims 19-21, Gertner et al. disclose the metallic matrix of the coating comprises an electrolessly electrochemically deposited (para 0048) and thus comprises a metal and a reducing agent of the metal (para 0036,0057).

Regarding claims 22-23 and 26-27, Gertner et al. disclose the metal may comprise nickel or cobalt and the reducing agent may comprise phosphorous (para 0056,0064).

Regarding claims 24 and 25, Gertner et al. disclose the first material may comprise stainless steel alloy or nitinol (para 0044).

Regarding claims 29-33, Gertner et al. disclose a second material may be formed between the first material and the coating material and a third material may be formed between the second material and the coating material since a plurality of layers may be formed with coating layers comprising bioactive material between metallic layers (para 0063). The second material may be electroplated metal such as nickel (para 0029, 0036, 0064), the third material may be a layer of electrolessly electrochemically deposited composite with metal and a reducing agent of the metal (0056-0058), and the coating may be another layer of electrolessly electrochemically deposited composite with metal and the reducing agent of the metal with the composite material (0051).

Regarding claims 34-37 and 39, Gertner et al. disclose the bioactive agent may be an anti-restenosis agent, an anti-inflammatory agent, an anti-proliferative agent, or a growth factor (para 0007, 0027, 0028).

Regarding claims 40-43, Gertner et al. disclose that by using an electroless deposition process, the percentage of bioactive material is controllable and thus the ratio of bioactive material to bioerodable material may be at least about 1.5:1 by adjusting the pH, temperature, and the constituents of the deposition bath accordingly (para 0068)."

Amendment to Independent Claim 1:

Applicant has amended Claim 1 to now clarify that the claimed stent system requires:

(a) a first porous substrate material on a stent surface; and
(b) a second composite material that
(i) is different than the first substrate material,
(ii) comprises a bioerodable material in combination with a bioactive agent, and
(iii) is located within the pores of the first substrate material.

Applicant's amended Independent Claim 1 thus requires two distinctly different materials: a first material that is the porous stent surface, and a second material which is a composite of bioerodable and bioactive materials. It also requires that this bioerodable/bioactive composite material is located in the pores of the uniquely different, first porous substrate material.

Applicant also described exemplary benefits contemplated with respect to this specific combination of features, including without limitation as follows at paragraph 00153 in the originally filed specification of the present application:

> "...because such bioerodable composite material is held within micro or nano-pores at the surface, such composite material not thus required to provide the structural integrity as a robust surface coating or structural component as is typically required by other conventional bioerodable approaches to drug delivery, in particular from stents or stent coatings. As such, it is considered a further benefit to allow for more drug loading, and less polymer, than such conventional approaches. For example, with respect to electroless electrochemical deposition, the required amount of polymer component in the composite is limited only to that amount as is required to maintain particle integrity and prevent substantial dissolving during the deposition bath process. It is considered therefore that much more drug, and less polymer, may be used in such applications versus other prior disclosures, thus reducing polymer burdens into tissues and improving biocompatibility and inflammation process." *Present Application, Para [00153].*

In contrast, Gertner does not disclose or suggest this combination of features, including in particular at the various locations within that disclosure which were cited under the current grounds for rejection in the recent Office Action.

More specifically, paragraphs 0011 and 0050 of Gertner, which provided the alleged basis for rejecting Claim 1 in the Office Action, actually state:

> "Embodiments of the invention are directed to structures, methods, and devices that include a metallic matrix including a bioactive material (e.g., a drug). In embodiments of the invention, the bioactive material is contained within a metallic matrix. In some embodiments, the matrix can be crystalline and can have grain boundaries. Diffusion of the bioactive

material can occur along the grain boundaries and crystallites of the metal. The bioactive material can be within, for example, nanometer and sub-nanometer sized voids in the metallic matrix. In embodiments of the invention, the bioactive material can be stored in the metallic matrix and can then be released from the metallic matrix. The bioactive material may diffuse through the metallic matrix or the metallic matrix could erode (actively and/or passively) to release the bioactive material over time. This can be done without using a polymeric storage and release medium for the bioactive material." *Gertner et al., para [0011](emphasis added).*

"The bioactive material may also comprise particles (e.g., in the size range of 0.1 to about 10 microns). The particles may comprise the bioactive material in a crystalline form. Alternatively, the particles comprise a polymer, ceramic, or metal, which can store a bioactive material. The particles are preferably insoluble in the electrochemical solution. In this case, a particulate stabilizer such as a surfactant could be added to the electrochemical solution to improve the homogeneity of the particles in the solution." *Gertner et al., para [0050] (emphasis added).*

The Office Action erroneously cited to Gertner when stating: "The stent is coated with a metallic matrix, which has pores containing a composite material comprising a plurality of particles of a bioactive agent stored in an *erodable* polymer (para 0011, 0050)" The "erodable" characteristic given to the polymer in this recitation was inserted by the Examiner in the context of the overall combination addressed; whereas conversely, Gertner neither discloses nor suggests locating erodable polymer carriers with bioactive agents discretely within the pores of a coating layer. Rather, Gertner merely refers to a polymer as one type of material in a list "which can store a bioactive material" when addressing particulates that may be co-deposited within a bioactive composite coating layer consistent with its disclosure. Gertner, para [0050]. The only characteristic given to polymer particulates in the co-deposition coating context is that it is preferably "insoluble in the electrochemical solution." Gertner references *erodable* polymers with respect to a "topcoat" that goes *over* (vs. *within*) the metal matrix bioactive composite surface layer of its disclosure (Gertner, Para [0078, 0079]). This is provided in a section of its disclosure entitled "C. Subsequent Processing" that follows each of sections "A. Substrate Preparation" and "B. Electrochemical Processes" in which the bioactive composite layer is formed. Gertner further discloses use of such

"topcoat" layer(s) in order to control release of the bioactive agent from its respectively disclosed bioactive composite coating. The "erosion" reference by Gertner in paragraph [0011] of that disclosure, as referenced in the present Office Action rejection, addresses eroding the metal matrix coating layer itself, not a discrete erodable material from within the pores of that coating layer.

In contrast to the Gertner disclosure, the system of Applicant's Independent Claim 1 (as currently amended) provides the ability to control release of bioactive agents from porous surfaces via erodable materials that carry the bioactive agent within, and that releases the bioactive agent from, pores provided by another coating material. This difference allows for a controlled release system from a single composite coating layer by means of the eroding drug carrier in the coating pores. This provides a beneficial overall bioactive coating structure that functions in a manner not previously provided, and clearly distinct from the Gertner disclosure. More specifically, Gertner neither describes nor suggests controlling the bioactive agent release from a stent surface by means of eroding the carrier of the bioactive agent from within the pores of a surface coating as one overall bioactive composite layer.

It is thus clear that loading pores of one coating material with another composite of bioerodable material plus bioactive agent, as is currently required by Applicant's amended Claim 1, is neither taught, nor is suggested, nor provides an expected result or is otherwise rendered obvious to one of ordinary skill upon review of the Gertner disclosure.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of this present ground for rejecting Claim 1 and all remaining claims that depend therefrom, and that this claim and all further claims in the Application that depend therefrom be allowed.

Additional Dependent Claims (Depending from Independent Claim 1)

Applicant further notes that various additional claims that depend from independent Claim 1 remain in the present application. These dependent claims are either preserved in their original form or are also hereby amended to clarify certain aspects captured by the particular claim(s). These claims variously provide further distinguishing features over the presently known art, including the Gertner disclosure cited in the present rejection. This is in particular the case with respect to the overall combinations of features claimed through dependency, which incorporate by reference the distinguishing features of Claim 1 as noted above. Accordingly, Applicant respectfully requests that these dependent claims be allowed in the context of incorporating allowable Claim 1 through dependency.

In addition, however, the further features and aspects noted in these dependent claims also provide additional separation from the disclosed art that Applicant submits are sufficient to render such claims allowable over and above the basis from respectively incorporated Claim 1.

Dependent Claims 12-15

In one particular regard, Claims 12-15 were rejected under the Office Action in view of Gertner. Applicant's Claim 12, as presently amended, requires that the first porous outer surface material is not inherently porous, and the pores are formed at discrete locations within the first material along the surface. Claims 13, 14, and 15, as presently amended, each further depend from Claim 12 and require that the pores are laser cut, photochemically etched, and chemically etched, respectively, into the first material.

The Office Action stated that the applied Gertner reference discloses that the porous outer surface may comprise a material that is not inherently porous, and the pores are etched into the material (para 0044).

Applicant respectfully submits that this reading and application of the cited passage of the Gertner disclosure is misguided. More specifically, this section of Gertner is presented in its entirety below, in context of its relationship to the overall disclosure, as follows:

"[0042] A. Substrate Preparation ...

[0044] The substrate may comprise any suitable material. For instance, the substrate may comprise a metal, ceramic, polymeric material, or a composite material. Illustratively, the substrate may comprise a metal such as stainless steel or nitinol (Ni—Ti alloy). Alternatively, the substrate may comprise a polymeric material including fluoropolymers such as polytetrafluoroethylene. In some embodiments, *the substrate may comprise a sacrificial material. A sacrificial material is one that can be removed, for example, by etching, thereafter leaving a free-standing bioactive composite structure.* ...

[0047] B. Electrochemical Process ...
[0069] C. Subsequent Processing"

This cited passage from Gertner clearly addresses a substrate preparation aspect of a three aspect process – Substrate Preparation, Electrochemical Process, and Subsequent Processing. Within this limited disclosure, it merely addresses etching away a substrate material to leave a bioactive composite behind as a "free-standing" structure. This passage does not disclose etching as a process involved in forming a bioactive composite material or layer, much less to specifically form pores into a bioactive composite material, as captured by Claim 12. Gertner does not appear to disclose, suggest, or other render obvious, either in the cited passage under the Office Action or elsewhere, deposition of any of its coating materials into discrete pores that are pre-formed, much less pre-formed by processing otherwise non-porous materials to

form pores that receive a deposited bioactive material, and still much less such a composite with bioerodable carrier. In fact, the Gertner disclosure appears to teach away from such a result in the following passage:

> "By co-depositing the bioactive material along with the metal, the concentration of the bioactive material in the bioactive composite structure is high. Moreover, the problems associated with impregnating porous structures with bioactive materials are not present in embodiments of the invention." *Gertner, Para [0052]*

Moreover, the allegation that this passage references "etching" pores, even if correct (which Applicant maintains it is not), still does not anticipate or render obvious the more specific requirements of the further detailed dependent claims 13-15, namely laser cutting, photochemically etching, or chemically etching, respectively.

Nonetheless, it is clear from a correct reading of the cited passage of Gertner that this disclosure neither anticipates, nor suggests or otherwise renders obvious, the system as recited in Claim 12 and subsequently Claims 13-15 through further dependency.

Dependent Claims 40-43

The Office Action also rejected dependent Claims 40-43 in view of Gertner, stating that para 0068 of Gertner allegedly discloses that by using an electroless deposition process, the percentage of bioactive material is controllable, and *thus that the ratio of bioactive material to bioerodable material* may be at least about 1.5:1 by adjusting the pH, temperature, and the constituents of the deposition bath accordingly.

In response, Applicant incorporates hereunder a portion of the recited paragraph of this reference as follows:

> "Forming a bioactive composite structure using an electroless deposition process is advantageous. First, by using an electroless deposition process, the size of the crystallites and consequent percentage of bioactive material is controllable. Parameters such as pH, temperature,

and the constituents of the deposition bath can be adjusted by the person of ordinary skill in the art to alter the volume percentage of bioactive material in the formed metallic matrix..." *Gertner et al., Para [0068](emphasis added)*

Applicant notes that Claims 40-42 subject to this ground for rejection have been maintained in their original form, and respectively recite that the ratio of the bioactive material to the bioerodable material in the composite material is at least about .5:1, 1:1, and 1.5:1, respectively. As noted in other remarks addressing other claims hereunder, Applicant's particular claimed embodiments that provide the bioerodable/bioactive composite within pores of another coating material allows for particular high ratios of bioactive material to bioerodable material, and considered to present higher ratio capabilities than other prior surface coating arrangements otherwise using similar bioerodable/bioactive composite component materials. This is because, among other benefits, the erodable carrier material is not required to provide other mechanical integrity, adhesion, or other characteristics typically required of that material in other prior surface coating applications when it is instead held within surface pores of another coating material, as is required by Applicant's present claims.

In contrast, the Gertner passage recited in the present rejection addresses how its coating environment may affect deposition ratios of bioactive agent within the metal matrix of the composite surface coating formed in an electrochemical co-deposition process. It does not address ratios of bioactive agent to bioerodable carrier material in a composite that is deposited within pores of another coating material, whether formed electrochemically, in co-deposition, or otherwise.

As Applicant's Claims 40-42 address ratios of bioactive agent to bioerodable material in a composite material held in pores of a coating material, and the recited portion of Gertner addresses a very different ratio of bioactive agent to the metal matrix material within which it is deposited, Applicant submits that the recited reference was misapplied against the subject matter of the original claims.

Applicant further notes with respect to Claim 43 that, though included in this ground for rejection, it is maintained in its original unamended form and does not relate in any specific manner to ratios of constituent components, but rather requires that the bioerodable material of the composite provided within the coating's pores be a bioerodable polymer.

Accordingly, Applicant submits that Gertner was misunderstood and as a consequence misapplied against the subject matter of original Claims 40-43, and respectfully requests reconsideration and withdrawal of this ground for rejecting these claims, and respectfully requests that these claims be allowed.

Independent Claim 44 (Currently Amended)

Applicant has amended independent Claim 44 to now clarify that the claimed stent system requires composite particles of bioerodable material plus bioactive agent be located within a coating material on a stent surface, such that the bioerodable material erodes and the bioactive agent is released from the coating material is implanted within a body of a patient.

The cited Gertner disclosure under the current ground for rejection does not provide such combination of features. As noted above with respect to remarks addressing this reference with respect to Claim 1, Gertner does not provide bioerodable materials in composite particles with bioactive agents within a coating layer. Nor does it disclose, suggest, or otherwise render obvious a coating environment to provide such result. Rather, that disclosure addresses other uses of erosion in different component aspects of a different layered composite system for drug delivery, and with different means to accomplish controlled drug delivery. Even where erosion in a bioactive layer

is noted in the Gertner disclosure, it is the metal matrix coating material itself that is alleged to erode. *Gertner, Para [0011].* This is distinctly different, and yields different results, than eroding a second material from within a first coating material. Moreover, one of ordinary skill would not expect, based upon a review of the Gertner disclosure, the beneficial results presented by Applicant's invention as captured by Claim 44, namely the various benefits gained by depositing a composite of bioerodable carrier plus bioactive agent within a different coating material layer for bioerosion and elution, respectively, from that coating.

Accordingly, Applicant respectfully requests that the present ground for rejecting independent Claim 44 be reconsidered and withdrawn, and that this independent claim and any claim that may depend therefrom be allowed.

Independent Claim 45 (Currently Amended)

Applicant has amended Independent Claim 45 to now clarify that the claimed system for depositing a bioactive coating onto a surface of an endolumenal stent requires (certain aspects of the presently amended language emphasized):

(a) a plurality of composite particles of bioactive agent plus bioerodable carrier material be located within a coating environment with metal ions; and

(b) the coating environment co-deposits the metal ions with the composite particles onto the endolumenal stent surface to form a composite surface coating when the endolumenal stent is exposed to the coating environment, such that the co-deposited composite surface coating is adapted to elute the bioactive agent therefrom and the bioerodable carrier material is adapted to erode therefrom when the surface is exposed to a body of a patient.

As previously noted above with respect to other Claims under rejection in view of Gertner, that cited reference does not disclose, suggest, or otherwise render it obvious to provide composite particles of bioerodable carrier plus bioactive agent within a

coating environment, much less in a manner that co-deposits the composite particles onto the stent surface, as Applicant requires in Claim 45 as currently clarified through the present amendment. Rather, as noted above, Gertner discloses only particulate characteristics as being preferably "insoluble" in its coating environment, and discloses erosion aspects only with respect to a deposited coating layer itself or with respect to a "topcoat" located over a bioactive composite layer in a multi layered coating system.

Accordingly, Applicant respectfully requests that the present ground for rejection be reconsidered and withdrawn with respect to Independent Claim 45, as currently amended and according to these remarks, and that this presently amended independent claim and any claim that may depend therefrom be allowed.

Independent Claim 46 (Currently Amended)

Applicant has hereunder amended Independent Claim 46 to now clarify that the claimed system for depositing a bioactive coating onto a surface of an endolumenal stent requires (aspects of amended language emphasized):

(a) a plurality of composite particles located within the coating environment and that comprise a composite material with a bioerodable material in combination with a bioactive agent; and

(b) wherein the coating environment is adapted to co-deposit a coating material together with the composite particles onto the surface so as to form a composite surface coating that is adapted to release the bioactive agent and erode the bioerodable material from the surface when the surfaced is exposed to a body of a patient.

As noted above with respect to other Claims under rejection, Gertner does not disclose, or suggest, or otherwise render obvious, such a coating system that provides composite particles of bioerodable material plus bioactive agent in a coating environment that co-deposits the composite particles together with another coating material to provide the erosion and elution as amended Claim 46 requires. Rather, as also noted above, Gertner discloses particulate "carrier" characteristics in its coating environment only as being preferably "insoluble" in that environment, and discloses

erosion aspects of materials or composite results only with respect to erodability of a deposited coating layer itself or with respect to a "topcoat" located over a bioactive composite layer in a multi layered coating system.

Accordingly, Applicant respectfully requests that the present ground for rejection be reconsidered and withdrawn with respect to Independent Claim 46, as currently amended and according to these remarks, and that this presently amended independent claim and any claim that may depend therefrom be allowed.

2. Rejections Under 35 USC § 103

a. Claim 28 was rejected under 35 USC 103(a) as being unpatentable over Gertner, as applied to claim 26, in view of U.S. Patent No. 6,120,536 ("Ding").

More specifically, as to this ground for rejection, the Office Action stated the following:

> Gertner et al. disclose the invention substantially as claimed including a stent (Fig 1, element 12) comprising a scaffold constructed from a first material and with a porous outer surface comprising a coating (10) with pores (14). The stent is coated with a metallic matrix, which has pores containing a composite material comprising a plurality of particles of bioactive agent stored in an erodible polymer (para 0011, 0050). The metallic matrix of the coating comprises is electrolessly electrochemically deposited (para 0048) and thus comprises a metal and a reducing agent of the metal (para 0036, 0057), where the metal may comprise nickel or cobalt and the reducing agent may comprise phosphorous (para 0056, 0064). However, Gertner et al. does not disclose the stent (first material) may comprise cobalt chromium alloy. Ding et al. disclose a similar stent structure that may be composed of a variety of materials including a cobalt chromium alloy. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Gertner et al. such that the stent was composed of a cobalt chromium alloy. Thus, manufacturing costs could be minimized by introducing more options for available materials and the marketability of the device would increase by having more available material options such that patients allergic to one material could use another for example.

Applicant has elsewhere herein noted with respect to independent Claim 1, from which this Claim 28 depends, that the reading and consequential application of Gertner in rejecting that base claim was misguided. In particular, Gertner neither discloses, suggests, or otherwise renders obvious deposition of a bioerodable material in composite with bioactive agent within pores of another coating surface material. Based upon this distinction alone, the features incorporated into Claim 28 merely through its dependency from Claim 1 should be sufficient to establish the allowability of Claim 28 over Gertner. In addition, however, Applicant further responds to this particular ground for rejecting Claim 28 as follows.

The subject Claim 28 has maintained its original antecedent claim dependencies, and thus depends from claim 26, which depends from claim 21, which depends from claim 20, which depends from claim 19, which depends from claim 18, which depends from claim 17, which depends from independent Claim 1. These claims, including Claim 28, have been variously herein amended. As a consequence, the subject matter currently recited in amended Claim 28 further limits the subject matter of Claim 1 by further specifying that, among other features:

(a) the endolumenal stent comprises a scaffold constructed from a cobalt-chromium alloy;
(b) the porous outer surface material comprises an electrolessly electrochemically deposited composite coating on the cobalt-chromium alloy substrate and that includes a cobalt metal and a reducing agent of the cobalt metal; and
(c) the pores which contain the bioerodable/bioactive composite material are located within the electrolessly electrochemically deposited cobalt-based composite coating.

The recent rejection notes that a cobalt-chromium alloy stent substrate is not disclosed in the recited Gertner reference, to which alleged defect in the applied reference the Office Action further combines the alleged disclosure of such stent alloy from the combined Ding reference. However, the rejection references an incomplete recitation of alleged benefits that may be afforded by the choice of cobalt-chromium.

This includes, for example, referencing benefits such as minimizing manufacturing costs, and providing patients with different allergies choices of metal substrates as the implants. While these in fact may be benefits provided by applying aspects of Applicant's present disclosure on different stent platforms to include cobalt chromium alloy, a significant, non-trivial, and unexpected beneficial result is provided by the specific combination of features provided in this claim and not recognized in the Office Action.

More specifically, what Claim 28 provides is a cobalt-chromium alloy stent in specific combination with a cobalt-based electrolessly electrochemically deposited composite surface coating. The cobalt-chromium alloy stent substrate comprises a leading form of stents due to its enhanced radiopacity, strength, and biocompatibility at particularly small stent scaffold sizes. These parameters are considered to themselves combat restenosis and other adverse results of the implants when compared with other stent alloys, including without the addition of any anti-restenotic drug elution added. In one particular regard, the cobalt-chromium is believed to form a particularly robust oxide layer considered to relate to enhanced biocompatibility. However, such tenacious oxides also typically render these surfaces particularly difficult to coat due to poor surface adhesion characteristics with conventional surface coatings.

However, in the system specifically captured by Claim 28, the cobalt-chromium alloy substrate is specially married with a cobalt-based electrochemical composite deposition. This combination allows for surface integration between the like cobalt components shared between the otherwise different composite layers of the resulting device. Significant benefit is thus presented by providing a cobalt-based coating in this manner on the cobalt-based stent substrate. This beneficial combination is not believed to be previously provided, nor believed to represent an expected result of prior experience or from a review of the recited disclosures. This is in particular the case in the setting, as required in Claim 28, where the cobalt-based composite coating on the

cobalt-chromium alloy stent scaffold holds a bioerodable/bioactive composite in its pores for erosion and elution, respectively, from the overall composite device.

Accordingly, in view of the allowability argued with respect to its respective base Claim 1, and in further view of the additional distinguishing remarks noted immediately above, Applicant respectfully requests reconsideration and withdrawal of this current ground for rejecting Claim 28, and that this claim and any claim that might further depend therefrom be allowed.

b. Claim 38 was rejected under 35 USC 103(a) as being unpatentable over Gertner, as applied to claim 1, in view of U.S. Patent Application Publication No. 2007/0037739 ("Wang").

More specifically, as to this ground for rejection, the Office Action stated the following:

> Gertner et al. disclose the invention substantially as claimed including a stent (Fig 1, element 12) comprising a scaffold constructed from a first material and with a porous outer surface comprising a coating (10) with pores (14). The stent is coated with a metallic matrix, which has pores containing a composite material comprising a plurality of particles of a bioactive agent stored in an erodible polymer (para 0011, 0050). Furthermore, the bioactive agent may be an anti-restenosis agent, an anti-inflammatory agent, or an anti-proliferative agent (para 0007, 0027, 0028). However, Gertner et al. does not disclose the bioactive agent may comprise des-aspartate angiotensin 1. Wang et al. disclose compounds useful in coating stents to treat restenosis including des-aspartate angiotensin 1 (para 0040, 0253-0261) which has been shown to substantially inhibit smooth muscle cells proliferation and drastically reduce restenosis (para 0261). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Gertner et al. such that the bioactive compound may also comprise des-aspartate angiotensin 1. Thus, the marketability of the device would increase and the stent may be more effective by effectively reducing restenosis.

Applicant has elsewhere herein argued with respect to independent Claim 1, from which this Claim 38 depends, that the reading and consequential application of Gertner in rejecting that base claim was misguided. In particular, Gertner neither discloses, suggests, or otherwise renders obvious deposition of a bioerodable material in composite with bioactive agent within pores of another coating surface material. Based upon this distinction alone, the features incorporated into Claim 38 merely through its dependency from Claim 1 should be sufficient to establish the allowability of Claim 38 over Gertner, including in combination with the Wang reference cited in the current ground for rejection. In addition, however, Applicant further responds to this particular ground for rejecting Claim 38 as follows.

The present Application provides specific examples that teach in fine detail electroless electrochemical coating depositions of DAA-1 on stents. In the realm of surface coatings, and in particular co-deposition environments such as electroless electrochemical settings, the ability to achieve particular combinations of coating substrates and elution substrates does not necessarily represent expected results to one of ordinary skill. This is even the case based upon knowledge of the existence of the general coating deposition process, or its adaptation to other compounds for elution, and the desired drug intended for inclusion for elusion from that coating.

In the present case, DAA-1 is a 10 amino acid peptide. The ability to appropriately coat this material in a robust manner onto a stent using a particular process, and including for a particular elution profile result, may depend upon a number of factors, including without limitation crystallinity, solubility, pH sensitivity, and other characteristics of the bioactive agent as it may be affected by or integrate appropriately into the coating process. For example, DAA-1 is generally considered more water soluble than many other known bioactive agents, in particular anti-restenotic agents, such as for example as compared against paclitaxel or sirolimus-type compounds. In the particular setting of electrochemical co-deposition, increased water solubility may degrade the co-deposition process or at least limit options. The present application

provides specific Examples where DAA-1 was observed to deposit onto stents and elute therefrom in an extended manner over at least 48 hours. However, DAA-1 may, if deposited alone without a companion carrier in composite form, limit desired variability of a deposition process to optimize intended results. Various broader aspects of the current disclosure and claims providing bioactive agent co-deposited within a surface coating porosity in composite form with a bioerodable carrier material presents particular benefits that would be unexpected from a review of Gertner or Wang, or both in conjunction. This includes in particular as applied to DAA-1 within that system, as required by Claim 38. A desire to enhance DAA-1's compatibility in surface coating processes or the resulting coatings themselves is not itself necessarily apparent to one of ordinary skill based upon the cited references or other information generally available to one of ordinary skill.

Accordingly, Applicant submits that the system of Claim 38, as applied to DAA-1, does not merely represent an obvious combination between Gertner and Wang disclosures. The present application includes positive experimental data results of DAA-1 deposition and elution on and from stents, respectively, that are not necessarily predictable based upon that combination of disclosures. Furthermore, these experimental results are disclosed in combination with revelations in the present Application that various benefits are afforded by providing certain bioactive agents, such as DAA-1, in composite form with bioerodable carriers within pores of other surface coating materials.

Applicant therefore submits that the Office Action failed to meet the requirements of a prima facie finding that the recited system of Claim 38, as limited by all of its required elements, would have been obvious to one of ordinary skill by modifying the device of Gertner such that the bioactive compound may also comprise des-aspartate angiotensin 1 as disclosed in Wang. Even if these two references were appropriately reviewed in combination by one of ordinary skill, desired results of the combination may not be achieved as would be expected, and other elements of the overall claim as noted

above still remain missing in such combination and are not adequately addressed as obvious variants in the Office Action.

Accordingly, in view of the allowability argued with respect to its respective base Claim 1, and in further view of the additional distinguishing remarks noted immediately above, Applicant respectfully requests reconsideration and withdrawal of this current ground for rejecting Claim 28, and that this claim and any claim that might further depend therefrom be allowed.

3. Amendments Made without Prejudice, Estoppel, or Waiver

Applicant has herein amended the claims in order to provide clarity to certain distinguishing features that are intended to be captured in the scope of claims currently presented in the instant Application, and in order to expedite examination of the Application toward hopeful allowance and subsequent issuance. However, such amendments have been made without prejudice, estoppel, or dedication to the public of the original subject matter presented prior to such amendment. Applicant reserves the right to pursue such original scope, and including other aspects presented in the original disclosure in the future, such as through continuation practice for example.

4. Conclusion

Applicant submits that, by entry of the current amendments and accompanying remarks, each ground for rejection of the recent Office Action has been adequately addressed and overcome in this communication. No new matter has been added by the current amendments, which have been made principally to enhance the clarity of the language of the original claims with respect to the subject matter currently intended. Applicant therefore respectfully requests that the various grounds for rejection in the recent Office Action be reconsidered and withdrawn with respect to all claims previously rejected, and that a Notice of Allowance be issued as to all remaining claims in the Application consistent with the present amendments. In the event the Examiner

determines additional clarity or resolution is required as to certain matters that may remain open following this communication, Applicant further requests that the Examiner please consider contacting Applicant's undersigned representative noted below in order to arrange a telephone conference in attempt to expedite reaching such resolution prior to the Examiner taking further action without the benefit of such discussion.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

Dated: 02 jul 07

Joseph Taffy
Registration No. 50,973
CUSTOMER NUMBER: 45200

KIRKPATRICK & LOCKHART PRESTON GATES ELLIS LLP
1900 Main Street, Sixth Floor
Irvine, California 92614-7319
Tel: (949) 253-0900
Fax: (949) 253-0902
Email: ocipgroup@klgates.com